

### **REMARKS**

Claims 12-14, 16, 23-25, 27-29, 31, 32-34 are pending in the subject application. Claims 12, 16, 23, 25, 27, and 31 have been amended. New claims 32-34 are added. No new matter is raised by these claims amendments or additions.

#### **Double Patenting**

The Examiner provisionally rejects claims 12-16 and 23-25 under the judicially-created doctrine of obvious-type double patenting over co-pending application 09/842,111 in view of Gonzalez et al. (U.S. 6,015,673). Applicants respectfully submit that the present claims are not obvious in light of Gonzalez, as demonstrated below. However, if the Examiner still maintains the obvious-type double patenting rejection over co-pending application 09/842,111, Applicant will file a terminal disclaimer pursuant to 37 C.F.R. §§1.130(b) and 1.312, upon a showing by the Examiner that the claims at issue are in condition for allowance, and if the 09/842,111 claims have issued.

#### **Rejection of claims 12-16 and 23-25 under of 35 U.S.C. §112, First Paragraph - Written Description**

Claims 12-16, 23-25 and 27-31 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the claimed invention is not described in such a way that one of ordinary skill in the art would be convinced that the Applicant was in possession of the claimed genus at the time of filing.

The claims have been amended, thus rendering this ground of rejection moot. Accordingly, applicants request withdrawal of this ground of rejection.

#### **Rejection under 35 U.S.C. § 103(a)**

Claims 12-13, 15-16, 23, 24, 27, 28, 30 and 31 have been rejected under 35 U.S.C. §103(a) over Gonzalez et al. (U.S. Patent 6,015,673) in view of Willhauck et al. (Biotechniques

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(1998) 25:656-659) and further in view of Buck et al. (Biotechniques (1999) 27:(3)528-536).

Applicants respectfully disagree as Gonzalez does not teach each and every element of the claimed invention and Willhauck and Buck do not make up for these deficiencies. For instance, the present claims involve fixing a portion of a tumor sample in paraffin. Gonzalez does not teach or suggest this. The present claims involve isolating mRNA from the fixed and paraffin embedded (FPE) tumor tissue. Gonzalez does not teach or suggest this. The present claims involve amplifying mRNA from the FPE tumor tissue. Gonzalez does not teach or suggest this. The present claims also involve comparing expression levels of DPD in the amplified mRNA from the FPE tumor sample with a predetermined threshold level for DPD expression. Gonzalez does not teach or suggest this. Finally, the present claims involve determining a 5-FU regimen based on the difference in amount of DPD mRNA in the amplified mRNA as compared to the threshold level for DPD gene expression. Gonzalez does not teach or suggest this. Willhauck and Buck do not teach or suggest these missing elements and do not make up for the shortcomings of Gonzalez. Thus, applicants respectfully assert that the combination of Gonzalez, Willhauck and Buck do not teach nor suggest the claimed invention and therefore do not render the claims obvious. Accordingly, applicants respectfully request withdrawal of this ground of rejection.

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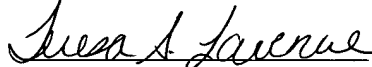
### CONCLUSION

It is believed that the present claims are in conditions for allowance and earnestly request allowance. Extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 11-0600. The Examiner is invited to contact the undersigned attorney if necessary to expedite allowance.

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Respectfully submitted,

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